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EXAMINER

BLIZZARD, CHRISTOPHER JAMES

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,857	Applicant(s) MADAUS ET AL.	
	Examiner CHRISTOPHER BLIZZARD	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-10 and 31-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10, and 31-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/19/10, 2/24/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This office action is in response to amendment filed 3/29/10. As directed claims 1, 7, 32, 34, 43, and 48 were amended, claims 6 and 11-30 were cancelled, and claim 58 was added. Therefore this application has claims 1-5, 7-10, and 31-58 pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5, 8, 32-37 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 5 recites the limitation "the portion defined thereby". There is insufficient antecedent basis for this limitation in the claim.

5. Claim 8 recites the limitation "the covering device". There is insufficient antecedent basis for this limitation in the claim.

6. Claims 32-37 recites the limitation "the entire front side of the mask" in second line of claim 32. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1-5, 10, 31-33, 35-37, 47, 50, 52, 53, 56, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen (6,357,440).

9. Regarding claim 1, Hansen discloses a respiratory mask comprising: a sealing portion for resting on and forming a seal with a facial surface of a mask user (fig. 1) the facial surface being around the nose or nose and mouth of a user (column 2, lines 14-16), a covering portion (104) which in cooperation with the sealing portion defines a mask interior (figs. 1 and 2), a headband arrangement (109) coupled to the covering portion (fig. 1), and a respiratory gas conduit (112) for delivering respiratory gas to the mask interior, wherein the respiratory gas conduit (112) is directly connected to the covering portion (104) (fig. 2), which is made of a woven material or non-woven material (column 2, lines 9-12).

10. Regarding claims 2 and 3, Hansen discloses the woven material being air permeable (column 2, lines 19-22), and thus inherently being porous in that it contains openings that allow air to pass through it.

11. Regarding claim 4, Hansen discloses the woven material being flexible (column 2, lines 17-19).

12. Regarding claim 5, Hansen discloses the area of the air permeability of the woven material being selected to produce sufficient outflow of gas from the mask interior (column 2, lines 40-45).

13. Regarding claim 10, Hansen discloses the sealing portion being integral with the covering portion (figs. 1 and 2).

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14. Regarding claims 31 and 58, Hansen discloses the woven material covering substantially an entire front side of the mask and covering portion (fig. 1).

15. Regarding claim 32, 33, 35 and 37, Hansen discloses the claimed respiratory mask above wherein the headband arrangement (109) is connected to the mask on lateral sides of the covering portion (fig. 1).

16. Regarding claim 36, Hansen discloses a receiving opening of the mask shaped to seal with the upper lip region and bridge of the nose region of the user (fig. 1).

17. Regarding claims 46, 47, and 52, Hansen discloses the claimed invention above, wherein the front side of the mask includes a gas outflow area (119) to provide diffuse outflow of gas from the mask interior to the atmosphere (column 2, lines 22-23), and the covering portion would inherently inflate when a gas is delivered to the interior of the mask due to its flexibility.

18. Regarding claim 50, Hansen inherently discloses the flexible portion of the mask having warp and weft threads with interstices there between because these of the characteristic of a permeable woven materials which the flexible portion is comprised of.

19. Regarding claim 53, Hansen discloses the flexible portion being made of a woven material and a layer of impermeable material (115) applied to the woven material (fig. 2).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440).

22. Regarding claim 8, Hansen discloses the claimed invention except for wherein the sealing portion is glue or vulcanized or sprayed onto a covering device. However, Hansen does disclose a coating (115) that could be applied as the sealing portion (column 2, lines 40-49), and it would have been obvious to one of ordinary skill in the art at the time of the invention that coating could be glue or vulcanized or sprayed on as these are well known coating application techniques.

23. Claims 7, 34, 48, 54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) as applied to claims 1, 32, and 46 above, and further in view of Grisbach (6,948,499).

24. Regarding claims 7, 34, 48, 54, and 56 Hansen discloses the claimed mask above except for the woven material comprising a GORE-TEX material. Grisbach teaches a mask with an exhaust area comprising a GORE-TEX material (column 6, lines 17-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the woven material of Hansen with a GORE-TEX material as taught by Grisbach in order to provide the advantage of better filtration.

25. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) as applied to claim 1 above, and further in view of Schwarz (2,931,356).

26. Regarding claim 9, Hansen discloses the claimed invention above except for the covering portion being detachably coupled to with the sealing portion. Schwarz teaches

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a respiratory mask with a detachable sealing portion (36) coupled to a mask (column 3, lines 43-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask of Hansen with a detachable sealing portion as taught by Schwarz in order to provide the advantage of a more comfortable seal.

27. Claims 38, 40-42, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) as applied to claim 1 above, and further in view of Maryyanek (4,600,002).

28. Regarding claims 38, 40-42, and 45, Hansen discloses the claimed mask above but does not disclose the flexible woven portion having a stitched seam segment.

Maryyanek teaches a mask comprising a woven material sewn together with a stitched seam (25). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask of Hansen with a stitched seam as taught by Maryyanek in order to provide the advantage of provide the mask with a shape that promotes a better seal.

29. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) as applied to claim 46 above, and further in view of Asplein (3,971,369).

30. Regarding claim 49, Hansen discloses the claimed mask above except for the flexible material being a plastic film having perforations. Asplein teaches a respiratory mask having a flexible mask body comprising a film having perforations (column 2, lines 26-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the covering portion of Hansen with a film having perforations in order to provide the advantage of precisely controlling the flow through the film.

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Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the perforated film be a plastic film, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

31. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) as applied to claim 46 above, and further in view of Bulmer (1,878,464).

32. Regarding claim 51, Hansen discloses the claimed invention except for the portion of the mask contacting the face of the user having an elastomer portion at least in the upper lip region. Bulmer teaches a respiratory mask with a flexible front portion with has an elastomer portion (10) along a region of the mask resting on the face of a user. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask of Hansen with an elastomer portion as taught by Bulmer in order to provide the advantage of a more secure fit.

33. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) and Maryyanek (4,600,002) as applied to claim 38 above, and further in view of Aspelin (3,971,369).

34. Regarding claim 39, the combination of Hansen and Maryyanek teach the claimed mask above except for the flexible material being a plastic film having perforations. Asplein teaches a respiratory mask having a flexible mask body comprising a film having perforations (column 2, lines 26-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the

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covering portion of Hansen and Maryyanek with a film having perforations in order to provide the advantage of precisely controlling the flow of gas through the venting portion of the mask. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the perforated film be a plastic film, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

35. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) and Maryyanek (4,600,002) as applied to claim 38 above, and further in view of Grisbach (6,948,499).

36. Regarding claim 43, the combination of Hansen and Maryyanek teach the claimed mask above except for the woven material comprising a GORE-TEX material. Grisbach teaches a mask with an exhaust area comprising a GORE-TEX material (column 6, lines 17-23). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the woven material of Hansen and Maryyanek with a GORE-TEX material as taught by Grisbach in order to provide the advantage of better filtration.

37. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) and Maryyanek (4,600,002) as applied to claim 38 above, and further in view of Bulmer (1,878,464).

38. Regarding claim 44, the combination of Hansen and Maryyanek teach the claimed invention except for the seal portion of the mask contacting the face of the user

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having an elastomer portion at least in the upper lip region. Bulmer teaches a respiratory mask with a flexible front portion with has an elastomer portion (10) along a region of the mask resting on the face of a user. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask of Hansen and Maryyanek with an elastomer portion as taught by Bulmer in order to provide the advantage of a more secure fit.

39. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) and Grisbach (6,948,499) as applied to claim 54 above, and further in view of Bulmer (1,878,464).

40. Regarding claim 55, the combination of Hansen and Grisbach teach the claimed invention except for the rear portion of the mask contacting the face of the user having an elastomer portion at least in the upper lip region. Bulmer teaches a respiratory mask with a flexible front portion with has an elastomer portion (10) along a region of the mask resting on the face of a user. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the mask of Hansen and Grisbach with an elastomer portion as taught by Bulmer in order to provide the advantage of a more secure fit.

41. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (6,357,440) and Grisbach (6,948,499) as applied to claim 54 above, and further in view of Aspelin (3,971,369).

42. Regarding claim 57, the combination of Hansen and Grisbach teach the claimed mask above except for the flexible portion being a film having perforations for gas

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outflow. Asplein teaches a respiratory mask having a flexible mask body comprising a film having perforations for gas outflow(column 2, lines 26-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the covering portion of Hansen and Grisbach with a film having perforations in order to provide the advantage of precisely controlling the flow through the film.

Response to Arguments

43. Applicant's arguments with respect to claims 1-5, 7-10, and 31-58 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

44. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771

/Steven O. Douglas/
Primary Examiner, Art Unit 3771